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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,950	11/25/2003	Russell Alan Parker	10030712-1	9616

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EXAMINER

PADGETT, MARIANNE L

ART UNIT	PAPER NUMBER
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1762

DATE MAILED: 09/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/722,950

Applicant(s)

PARKER ET AL.

Examiner

Marianne L. Padgett

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,18,27-29,53,55,57 and 59-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,18,27-29,53,55,57 and 59-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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1. Applicants' term disclaimer dated 6/21/2006 over SN 10/172,580 has been received and approved hence removes the obviousness double patenting rejection thereover in section 8 of the action mailed 3/22/2006.

2. Applicants have amended all their independent claims to require "at least one addressable array on said microarray substrate" or the like, however they cited no support therefore. Review of the specification shows disclosure of addressable arrays or addressable microarrays in paragraphs [0022] & [0025], where said addressable arrays are discussed as having multiple different regions with different "moieties" (e.g. ligands or receptors) that will be "detected" by particular classes of target materials, hence, having an array on the substrate be an addressable array is supported by the specification. Support for having plural such addressable arrays on one microarray substrate was more difficult to find in the jumbo specification, however [00131-132] on page 46 discuss that a substrate may carry "one, two, four or more arrays disposed on the surface of substrate...", and while plural arrays are never discussed with respect to addressable arrays, the discussion in [0022] is considered acceptable due to its discussion of addressable with respect to arrays in general in combination with [00131+] to provide sufficient support for the claimed amendments.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 28, 53, 57 & 61 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Audino et al. (2002/0083686 A1) discussed in section 4 of the 3/22/2006 action.

Applicants have amended their claims to require the array(s) in the sealed chamber to be "at least one addressable array", wherein these types of arrays that are on the microarray substrate can be considered to be an intended use that has no recognizable effect on the actual treating step for the gasket that is claimed. The examiner notes that "a backing element comprising a gasket, wherein said backing element is adapted to joining with a microarray substrate..." is not affected by whether or not the array that is on, or to be put on the substrate at some time, is addressable or not addressable, i.e. the gasket is adapted to join with the substrate, not what it's on the substrate.

While Audino et al. does not use this new claim language, one of their purposes for sealing their multiwell plates is to "minimize... crosstalk..." [0007] between wells on the multiwell plate (also see [0004] with employing multiwell plates for storing, reacting and/or analyzing liquid samples & [0009]), which suggests like intended use as claimed, since the wells clearly contained or are intended to contain different samples, or one would not need to minimize crosstalk, therefore it can be considered Audino et al.'s disclosure reads on the addressable requirement as the biological or chemical assays performed therein as the samples in the individual wells are suggested not be all the same, thus would be

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inherently addressable to some class of compound. Audino et al.'s process clearly seals the substrate with the multiwells into a multizone chamber, can be considered to be used for assays & is suggested to be directed towards "addressable" samples, hence applicant's arguments of differentiation are not convincing. Alternately, given Audino et al.'s intended use, it would have been obvious to one of ordinary skill in the art to use the sealed wells of the taught microtiter test plate in biological and chemical assays as taught, for which one would have been expected in many tests to have arrays with chemically different regions, which would have been "addressable" as claimed & defined.

To reiterate previous discussion, Audino et al (abstract; figures, especially 4-5b; [0002]; [0003-9] for background and problems; [0010]; [0020-21]; [0024-29]) teach a sealing member (i.e. gasket) made of an elastomeric material, which is employed to create a seal between a lid and a multi-well plate (microtiter test plate) that may be used in biological or chemical assays. The sealing member structure may be melt welded/sealed (i.e. joined) to the multi-well storage or test plate, or to the lid. Various structures, materials and means for producing elastomeric sheet sealing member are taught inclusive of multilayered structures, where an example for sealing polypropylene plates was given as using a polypropylene film or compatible material which is corona treated on one side, where it is noted that corona treatment is a species of plasma treatment (an analogous process for polystyrene film was also disclosed). The corona treated side was taught to be coated with a layer of partially epoxydized polybutadiene which is polarized to form a cross-linked monomer that is bonded to the thermoplastic film ([0028]), hence reading on the options of both depositing a material on the gasket structure and on the elected species of plasma modifying the surface of the gasket structure.

5. Claims 18, 27, 55 & 59-60 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Audino et al, as discussed in section 5 of the 3/22/06 action, and repeated below.

Audino et al do not teach what gases are employed when they corona treat their sealing members' surface, nor do they discuss whether or not the hydrophilicity of the surface is increased, however corona

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discharge processes are commonly done under atmospheric conditions, i.e. in air, hence it would have been obvious to one of ordinary skill in the art, that when no particular gases are disclosed as in Audino et al, to employ typical or old and well-known conditions for the taught corona process, and therefore to employ air in the treatment. It is further noted that since oxygen in the air is a major reactive component, that it would have been expected to effect oxygen functionalization of the polymeric surfaces so treated, which would have increased their hydrophilicity, especially for the exemplified polypropylene or polystyrene films whose initial structures contain no oxygen, so that the taught corona treatment thereof would have been expected to increase the hydrophilicity and thus increase the wettability of the coating that is applied thereafter.

6. Claims 29 & 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Audino et al as applied to claims 1, 16-18, 27-28, 53-55 & 57-61 above, and further in view of Gilmore et al. (2003/0207099 A1, previously discussed in section 8 of the 11/2/2005 action & repeated below).

Audino et al does not teach treating the sealing member surface (gasket) with sequential treatments of at least two treatments chosen from the group of plasma, or UV + O₂, or a solvent. However, it is noted that since cleaning procedures such as washing, which uses solvents are standard procedures in coating operations, it would've been obvious to one of ordinary skill and competence to clean, as by washing, the polypropylene or polystyrene surfaces of the sealing member before the corona treating and coating operations, as a matter of standard practice to ensure improved coating adherence due to removal of any contaminants.

Alternately, Audino et al also teaches the use of other materials, such as silicones (although less desirable, [0028]), hence it would have been obvious to one of ordinary skill in the art to employ treatments known to improve the wettability of silicone surfaces, such as those taught by Gilmore et al. (abstract; [0010-14]; [0025-28, esp.28]; & esp. [0030] + [0032]) for improving the wettability of silicones polymer membranes, such as polydimethylsiloxane (PDMS), in order to enable equivalent usability with

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the exemplified polypropylene or polystyrene. It is noted that Gilmore et al. teaches a process with two consecutive plasmas (e.g. O₂ plasma, then SiCl₄ plasma) to enhance and stabilize the wettability of PDMS membrane materials by hydrophilizing the surface, to enable subsequent coating/adhesion. These teachings with the applicable to any sealing member employed for analogous purposes of Gilmore et al. or Audino et al., as the process of improving the sealing interface would be equally applicable to structures that use like materials regardless of the particular configuration being sealed.

7. Claims 1, 18, 27-29, 53 & 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Desrosiers et al. (6,410,332 B1) or Dunnington et al. (6,376,256 B1) or Stanchfield et al. (6,054,100), in view of Matsuzawa et al (JP2000-300670 A).

The primary references to Desrosiers et al., or Dunnington et al., or Stanchfield et al. all teach the use of gaskets for joining multi-well structures for chemical sampling and analysis or synthesis, i.e. chemical reactions, where Desrosiers et al. (abstract; figures to & 5-6, reference numbers 64 & 72, 188, 238, respectively; col. 7, lines 57-col. 8, line 4; col. 10, lines 23-29; and col. 11, lines 24-30) teach that the gasket material can be any inert, resilient material that provides to stress relief and helps prevent migration of reaction mixture between components of the library members, i.e. between the wells, where the taught library members are considered suggestive of different moieties or the claimed addressable arrays; or where Stanchfield et al. (abstract; figures 1 & 12, reference numbers 18 & 20, or 106 & 108, respectively, which sealed the covers for the single chamber holding the array, where the full Sheik gasket of figures 1-3 also sealed the rims of the wells creating a multizone effect in the chamber, while the lip & base of figures 12-13 are secured by gaskets that only seal the peripheral regions of the entire chamber holding the array; col. 6, line 65-col. 7, line 7; col. 8, line 35-40; col. 9, line 55-col. 10, lines 5, 13-26 & 56-65; col. 11, lines 28-53, especially 45-50) teach the gaskets to be chemically resistant rubber materials as are well known to be used for forming septa for sealing of containers by researchers e.g. VITON or SANTOPRENE, with the "technical field" (col. 1, lines 10-15) indicate the use of this invention relates to

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synthesizing and culturing chemical and bacterial compounds by performing multiple simultaneous synthesis and filtration is on a micro scale, which is considered suggestive of the claimed "addressable" limitation, as the context (col. 1, lines 18-38+) clearly indicate that these are different simultaneous reactions, thus employ different moieties, hence are addressable; or where Dunnington et al. (abstract; figures 1,7 & 12, reference numbers 17, or 110, or 128 & 130, respectively; col. 4, lines 28-32; col. 9, lines 1-3 & 46-68) teach gaskets or elastomeric sheets made preferably of chemically resistant fluoroelastomer, such as material available under the trademark VITON, where in some cases the elastomeric seal only contacts around the periphery of the array as in seal 110 of figure 7 or seals individual capillaries for a multizone chamber effect as in the elastomeric sheet 128 of figure 12, depending on the type of reaction/results desired (col. 9, lines 44-46). Dunnington et al.'s teaching of combinatorial libraries in an array format (col. 1, lines 12-17) are also considered suggestive of the claimed "addressable" limitation. The previous arguments for "addressable" as discussed above in section 4, are also considered applicable with respect to the three alternative primary references discussed in this rejection.

However, none of these references give any details or more specific discussion on how the gasket or sealing member is formed or prepared, but all of these primary references suggest the need for chemically resistant materials, resilient materials and either chemically inert or fluoroelastomeric materials, thus providing guidance to one of ordinary skill on suitable materials for use as gaskets.

Matsuzawa et al, as discussed in the abstract & in the machine translation, provide a means for making rubber gaskets useful with syringes, that have satisfactory sealing properties with respect to medicinal fluids, hence relevant to the primary references for its stability to seal and protect against fluids contained in a cellular compartment. In the translation [0002] indicates gasket materials fabricated out of thermoplastic elastomers, with [0003] noting useful list of fluororesins. [0007], [0015-16] & abstract discuss that after a rubber gasket is molded or fabricated in an appropriate shape, it is plasma treated with

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at least one plasma gas of H₂, N₂, O₂, F₂, a fluoride or an "inactive" gas; thereafter it is exposed to a plasma of a hydrocarbon gas. In [0010] notes the outstanding chemical stability of the produced gasket such that it prevents pollution due to migration of solutions contained by the syringe and gasket, while in the part of paragraph [0011] at the top of p.3 & [0013], desirable physical properties for the completed gasket are discussed, including appropriate deformability for use as a gasket. Therefore, it would have been obvious to one of ordinary skill in the art to employ gasket forming procedures as suggested by Matsuzawa et al to create specific configurations as desired in any of the primary references, in order to provide a gasket with satisfactory sealing properties in the presence of fluids, as well as suitable deformability or resilience. Note that the use of 2 separate plasmas can be considered to read on the "at least two" choice of claims 29 & 62, while the use of O₂ on the rubber would have been expected to increase the hydrophilicity of the rubber surface.

8. Claims 1 & 28 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Arthur Schleifer (2003/0231985 A1), discussed in section 8 of the 3/22/06 rejection.

As previously stated, Schleifer, while the semantics are different, teaches configurations of the gasket and assay chamber of the two cases are of overlapping scope, and the curing process applied to the gasket material of Schleifer can be considered to be read on by the claimed treating options of the present case, because the curing will modify/treat the surface of the deposited gasket and be done in the presence of atmosphere inclusive of the claimed "contacting said gasket with a vapor phase), which is directed to no particular effect or context. Alternately as no particular conditions are taught as required for the curing of the gasket material, it would've been obvious to one of ordinary skill in the art to cure in air which is inclusive of containing vapor components which will necessarily contact the service during this treating operation. It is noted that the amendment of claim ones option (2) from the more specific "extracting a component close quote to the more general "contacting said gasket" removes any context of

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what effect option number two has while the addition of "with at least one of a liquid phase or a vapor phase" is so broad to include such steps as merely washing the gasket at some time in its life, such that with the teachings in [0039] that the gasket formed may be reusable, it would have been obvious to one of ordinary skill in the art that it one is reusing a gasket that has been used for a previous set of assays, that it is necessary to wash it in order to form a good seal for the next set of assays to be performed, thus reading on applicants very broad option (2), providing a further alternative reason for obviousness.

Note that the primary reference explicitly teaches addressable arrays in [0033].

It is noted that this publication to Arthur Schleifer, while by a different inventor appears to be to the same assignee as shown by the patent application publication 2003/0231985 A1 of this application & the supplied TD, hence as the filing date of this application (6/14/2002) is before the present filing date of 11/25/2003, and there are no overlapping inventors rejection under 102/103 remains appropriate, as no statement of common ownership at the time of the invention has been made by an attorney of record.

9. Claims 1, 18, 27-29, 53, 55, 57, & 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blackburn (6,875,619 B2), in view of Matsuzawa et al (JP2000-300670 A, discussed above).

Blackburn is teaching substrates called biochips that have one or more arrays thereon with a plurality of binding ligands that may be called a addressable (column 22, line 61-column 23, line 9 & column 24, line 5-line 21). Their teachings include well structures surrounded by o-rings or gaskets, which may be made of materials such as rubber and silicone, that encompass whole arrays to dust form what may be called an assay chamber (figures 20-24 & 32, etc.; column 51, lines 55-57 column 52, lines 26-32 & 57-68+; col. 62, lines 40 (especially 53-59 with oh rings or gaskets of rubber or silicone)-column 64, line 55, especially col. 64, lines 18-55; col. 68, lines 57-67+; col. 69, lines 17- 25, etc.),. Blackburn et al. differs from the claims by not teaching any particular treatments for the gaskets or o-rings, however Matsuzawa et al as discussed above in section 7, presents reasons and benefits for providing treatments as

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claimed to effect superior sealing of analogous enclosures for purposes which would've been expected to provide benefits as taught for the enclosures formed in Blackburn, including reasons as previously discussed above, hence it would've been obvious to one of ordinary skill in the art to apply such treatments to analogous sealing members as required by the teachings of Blackburn in order to effect such benefits.

10. Other art of interest include grass (6146883) who teaches space eagerly addressable arrays in housing bases sealed by a lid; Rava et al. (5545531) & Schembri (2004/0087033 A1; [0109]), with teaching similar to Blackburn.

11. Applicant's arguments filed 6/21/2006 & discussed above in context of each rejection have been fully considered but they are not persuasive.

While there seems to be some hint from applicant's argument that they might intend that gasket be used for sealing a single chamber, with no sub-chambers or internal sealing within the chamber, the claim language does not necessarily exclude such sub chambers, hence applicants arguments that might hint at this possibility are not convincing. While some of the previously applied art suggest single chamber's with the array within, the newly applied reference to Blackburn more explicitly discloses concepts that may be intended by applicants' amended claim language & arguments.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

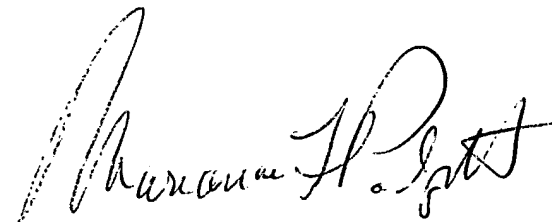
13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne L. Padgett whose telephone number is (571) 272-1425. The examiner can normally be reached on M-F from about 8:30 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks, can be reached at (571) 272-1423. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MLP/dictation software

9/3 & 5/2006

A handwritten signature in black ink, appearing to read "Marianne L. Padgett", written in a cursive style.

**MARIANNE PADGETT
PRIMARY EXAMINER**